PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

James E. GALEN

Conf. No.: Unassigned

DIVISIONAL

Appln. No.: of 09/453,313

Group Art Unit in Parent: 1636

Filed: January 5, 2004

Examiner in Parent: Guzo, D.

For:

PLASMID MAINTENANCE SYSTEM FOR ANTIGEN DELIVERY

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.97 and 1.98

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 CFR §1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form which are all the references of record in parent application No. 09/453,313. Applicant is not submitting duplicate copies of these references, but requests that they be listed on the face of any patent granted on the above application (see 37 C.F.R. §1.98(d)).

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

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WASHINGTON OFFICE 23373
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Date: January 5, 2004

Respectfully submitted,

Drew Hissong

Registration No. 44,765

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Application Number	DIV of USSN 09/453,313		
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First Named Inventor	James E. GALEN		
Art Unit	1636		
Examiner Name	Guzo, D.		
Attorney Docket Number	A-8702		

			U.S. PATENT DOCUMENTS					
Examiner Cite		Document Nu		Publication Date				
Initials*	No.1	Number	Kind Code ² (if known)	MM-DD-YYYY	Name of Patentee or Applicant of Cited Document			
		US 4,735,801		04/05/1998	Stocker			
		US 4,764,370	1	08/16/1988	Fields et al			
		US 5,459,072		10/17/1995	McKay et al			
		US 5,643,771		07/01/1997	Stocker			
		US 5,672,345		09/30/1997	Curtiss III			
	_	US 5,695,983		12/09/1997	Miller et al			
		US 5,763,270		06/09/1998	Eastman et al			
		US 5,770,214		06/23/1998	Dougan et a;			
		US 5,804,194		09/08/1998	Dougan et al			
		US 5,851,519	-	12/22/1998	Dougan et al			
		US 5,674,703		10/07/1997	Woo et al			
1		US 5,527,529		06/18/1996	Dougan et al			
		US 4,760,022		07/26/1998	Molin et al			
		US 5,853,718	Ì	12/29/1998	Molin et al			
		US 5,922,583		07/13/1999	Morsey			
T i		US 5,545,541		08/13/1996	Molin et al			
		US 5,824,538		10/20/1998	Branstrom et al			

FOREIGN PATENT DOCUMENTS							
Examiner	Cite	For	eign Patent Docum	ent	Publication Date	Name of Patentee or	m
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		NON PATENT LITERATURE DOCUMENTS		
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		Summers, The Biology of Plasmids, pages 65-91 (1996)		
		Jensen et al, Molecular Microbiology, 17(2):205-210 (1995)		
		Pecota et al, Applied and Environmental Microbiology, 63(5):1917-1924 (1997)		
		Boe et al, Journal of Bacteriology, 169(10):4646-4650 (1987)		
		Gerdes et al, Annu. Rev. Genet., 31:1-31 (1997)		
		Gultyaev et al, J. Mol. Biol., 273:26-37 (1997)		
	Franch et al, J. Mol. Biol., 273:38-51 (197)			
	Mikkelsen et al, Molecular Microbiology, 26(2):311-320 (1997)			
		Franch et al, Mol. Microbiol., 21(5):1049-1060 (1996)		
		Gerdes et al, J. Mol. Biol., 190:269-279 (1986)		
		Gerdes et al, Genetic Eng., 19:49-61 (1997)		
		Gerdes et al, J. of Bacteriology, 161(1):292-298 (1985)		
		Wu et al, Biotechnology and Bioeng., 44:912-921 (1994)		
		Wood et al, Biotechnology and Bioeng., 38:397-412 (1991)		
		Gerdes, Biotechnology, 6:1402-1405 (1998)		

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		Bravo et al, Mol. Gen. Genet., 210:101-110 (1987)	
		Ruiz-Echevarria et al, <i>Mol. Microbiol.</i> , 5(11):2685-2963 (1997)	
		Ruiz-Echevarria et al, Gen. Genet., 248:599-609 (1995)	
		Ruiz-Echevarria et al, J. Mol. Biol., <u>247</u> :568-571 (1995)	
		Bravo et al, Mol. Gen. Genet., 215:146-151 (1988)	
		Nordstrom et al, "Control of Replication of Bacterial Plasmids: Molecular Biology,	
		and Physiology of the Plasmid R1 System", Academic Press Inc., pages 71-91 (1984)	
		Gerdes et al, "Antisense RNA-Regulated Programmed Cell Death", Annual Rev. Inc, pages 1-31 (1997)	
		Nordstrom et al, BIOSCI, pages 294-300 (1994)	
		Pedersen et al, Mol. Microbiol., 32(50):1090-1102 (1999)	
		Melton-Celsa et al, "The Structure, Biology, and Relative Toxicity for Cellsa dna Animals of Shiga Toxin	
		Family Members", Uniformed Services University of the Health Sciences, pages 1-23	
		Dolfing et al, ASM News, <u>62(3)</u> :117-119 (1996)	
		Keeler et al, Handbook of Natural Toxins, 8:313-327	
		Konowalchuck et al, <i>The Lancet</i> , 351:1003 (1998)	
		Endo et al, Eur. J. Biochem., <u>171</u> :45-50 (1988)	
		Gerdes et al, Proc. Natl. Acad. Sci., USA, 83:3116-3120 (1986)	
		Gyles, Can. J. Microbiol., 38:732-746 (1992)	
		Jackson et al, Federation of European Microbiological Societies, 44:109-114 (1987)	
		Tesh et al, Inf. and Immun., 61(8):3392-3402 (1993)	1
		Lindgren et al, Inf. and Immun., 62(2):623-631 (1994)	
		Sung et al, J. of Bacteriol., 172(11):6386-6395 (1990)	
		Muhldorfer et al, Inf. and Immunol., 64(2):495-502 (1996)	
		Schmitt et al, <i>Inf. and Immunol.</i> , 59(3):1065-1073 (1991)	
		Weinstein et al, J. of Bacteriol., 170(9):4223-4230 (1988)	
		Gyles et al, Microbial Pathogenesis, 5:419-426 (1988)	1
		Paton et al, Infect. and Immunity, 63(7):2450-2458 (1995)	
		Paton et al, Microbial Pathogenesis, 15:77-82 (1993)	1

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		Stein et al, <i>Nature</i> , <u>355</u> :748-750 (1992)	
		Per-Georg et al, Int. J. Biol. Macromol., 17(3-4):199-204 (1995)	
		Per-Georg et al, Chemistry & Biology., 3(4):263-275 (1996)	
		Ling et al, Biochemistry, 37:1777-1788 (1998)	
	_	Hovde et al, Proc. Natl. Acad. Sci., USA, 85:2568-2572 (1988)	
		Yamasaki et al, Microbial Pathogenesis, 11:1-9 (1991)	<u> </u>
		Jackson et al, J. of Bacteriology, <u>172(6)</u> :3346-3350 (1990)	
		Gordon et al, Inf. and Immun., 60(2):485-490 (1992)	
		Bosworth et al, Inf. and Immun., 64(1):55-60 (1996)	
		Jackson, J. of Bacteriology, 172(2):653-658 (1990)	
		Clark, Mol. Microbiology, 19(4):891-899 (1996)	1
		Bast, Inf. and Immun., 65(6):2019-2028 (1997)	
		Perera et al, J. of Bacteriology, <u>173(3)</u> :1151-1160 (1991)	
	_	Perera et al, Inf. and Immun., <u>59(3)</u> :829-835 (1991)	
		Downes et al, Inf. and Immun., 56(8):1926-1933 (1988)	
		Su et al, Inf. and Immun., 60(8):3345-3359 (1992)	
		Su et al, Microbial Pathogenesis, 13:465-476 (1992)	
		Richardson et al, <i>Inf. and Imm.</i> , 60(10):4154-4167 (1992)	
		Nelson et al, "Biological Activity of Verocytotoxin (VT)2c and VT1/VT2c chimeras in the rabbit model", Elsevier Science, pages 245-249 (1994)	
		Bielaszewska et al, Inf. and Immun., 65(7):2509-2516 (1997)	
		Streatfield et al, Proc. Natl. Acad. Sci., USA, 89:12140-12144 (1992)	1
		Acheson et al, Inf. and Immun., 64(1):355-357 (1996)	
		Wadolkowski et al, Inf. and Immun., 58(12):3959-3965 (1990)	
		Karpman et al, J. of Infect. Dis., <u>175</u> :611-620 (1997)	
		Louise et al, J. of Infect. Dis., <u>172</u> :1397-1401 (1995)	
		Boyd et al, Nephron, 51:207-210 (1989)	
		Zoja et al, J. Lab. Clin. Med., 120(2):229-238 (1992)	

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		McDaniel et al, Proc. Natl. Acad. Sci., USA, 932:1664-1668 (1995)	
		Jarvis et al, Proc. Natl. Acad. Sci., USA, <u>92</u> :7996-8000 (1995)	
		Jarvis et al, Inf. and Immun., 64(11):4826-4829 (1996)	
		Sixma et al, <i>Biochemistry</i> , <u>32</u> :191-198 (1993)	
		Mangeney et al, Cancer Res., <u>53</u> :5314-5319 (1993)	
		Franke et al, J. of Clin. Microbiology, <u>33(12)</u> :3174-3178 (1995)	
		Kim et al, Micro. Immunol., 41(10):805-808 (1997)	
		Butterton et al, Infect. and Immunity, <u>65(6)</u> :2127-2135 (1997)	
		Nataro et al, Amer. Soc. for Microbiology, 11:164-178 (1998)	
		Taga et al, <i>Blood</i> , <u>90(7)</u> :2757-2767 (1997)	
		Haddad et al, J. of Bacteriology, 175(16):4970-4978 (1993)	
		Gannon et al, <i>J. of General Microbiology</i> , <u>136</u> :1125-1135 (1990)	
		O'Brien et al, <i>Micro. and Immunol.</i> , <u>180</u> :66-93 (1992)	
		Montfort et al, J. of Biological Chem., 262(11):5398-5403 (1987)	
		Lindgren et al, Inf. and Immun, 61(9):3832-3842 (1993)	
		Rasmussen et al, Mol. Gen. Genet., 209(1):122-128 (1987)	
		Gerdes et al, Mol. Microbiol., 4(11):1807-1818 (1990)	
		Ito et al, Microbial Pathogenesis, 8:47-60 (1990)	
		Fraser et al, <i>Structural Biology</i> , <u>1(1)</u> :59-64 (1994)	
		Yu et al, Mol. Microbiol., <u>6(3)</u> :411-417 (1992)	
		Thisted et al, J. Mol. Biol., <u>247</u> :859-873 (1995)	
		Thisted et al, <i>The EMBO Journal</i> , <u>13(8)</u> :1950-1959 (1994)	

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